Appendix XV.

COMPARISON OF OW AND OPP METHODS FOR AQUATIC ASSESSMENTS

CATEGORY	OW	OPP
APPROACH USED TO ESTABLISH LEVEL OF PROTECTION	Establishes numerical ambient water quality criteria only if all required data are available. Develops a Criterion Continuous Concentration (CCC) and a Criterion Maximum Concentration (CMC) which are concentrations that should not result in unacceptable effects of aquatic organisms and their uses. Except possibly where a locally important species is very sensitive, aquatic organisms and their uses should not be affected unacceptably if the four-day average concentration of a chemical does not exceed the CCC more than once every three years on the average and if the one-hour average concentration does not exceed the CMC more than once every three years.	Uses "Quotient Method", whereby an Estimated Environmental Concentration (EEC) is compared to an effect level, usually an LC50 for acute effects and an NOAEC for chronic effects. The resulting ratio of EEC to effect level, also referred to as the Risk Quotient (RQ), is compared to a Level of Concern (LOC). EECs are developed from Tier I or Tier 2 surface water models. The Tier 1 model, GENEEC, estimates surface water concentrations from both runoff and spray drift from a 10-hectare field immediately adjacent to a 1-hectare pond that is 2 meters deep and has no outlet. The contribution of pesticide is based on a single application of pesticide followed by a storm event that causes 10 percent runoff of the applied pesticide into the adjacent pond. The contribution of pesticide from spray drift, however, is estimated based on spray drift that is associated with each application of pesticide. Data on fate processes such as hydrolysis in water, photolysis in soil, aerobic soil metabolism, aerobic aquatic metabolism, and sorption of pesticide onto soil are accounted for in estimating surface water concentrations. If RQ values based on EECs estimated from GENEEC exceed LOCs, EECs are subsequently estimated from a Tier 2 model, PRZM/EXAMS, which includes more detailed information on crop site characteristics than GENEEC. For each crop for which pesticide application is proposed, PRZM/EXAMs includes a single location to represent a typical upper-end scenario. Generally, weather and agricultural practices are simulated over 36 years so that the 1 in 10 year annual return frequency at the representative location can be estimated. This annual return frequency corresponds to the 90^{th} percentile annual exceedance that was determined over the 36-year period that was modeled. The 90^{th} percentile annual exceedance is determined by ranking from highest to lowest the dissolved water column concentrations for each of the 36 years modeled and determining the 90^{th} percentile of these values. The EEC can also be based on monitoring data, if available.

CATEGORY	OW	OPP
DERIVATION OF LEVELS OF PROTECTION	The CMC is an estimate of the concentration of material corresponding to a cumulative probability of 0.05 in the acute toxicity values for the genera with which acceptable acute tests have been conducted on the material. The CMC is intended to protect 95 percent of a group of diverse genera, unless a commercially or recreationally important species is very sensitive. The Criterion Maximum Concentration (CMC) is based on one-half the final acute values for fresh and salt water. The Final Acute Value is derived from Genus Mean Acute Values, the geometric means of all the Species Mean Acute Values for species in the genus. The Criterion Continuous Concentration (CCC) is intended to be a good estimate of a threshold of unacceptable effect, not a threshold of adverse effect. The CCC is equal to the lowest of the Final Chronic Value, the Final Plant Value, and the Final Residue Value, unless other available data concerning adverse effects on aquatic organisms and their uses show that a lower value should be used. The Final Chronic Value might be calculated in the same manner as the Final Acute Value or by dividing the Final Acute Value by the Final Acute-Chronic Ratio. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis. The Final Plant Value should be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentration of test material was measured and the endpoint was biologically important. The Final Residue Value is the lowest of the residue values that are obtained by dividing maximum permissible tissue concentrations by appropriate bioconcentration or bioaccumulation factors. A maximum permissible tissue concentration is either an FDA action level for fish oil or the edible portion of fish or shellfish, or a maximum acceptable dietary intake based on observations of survival, growth, or reproduction in a chronic wildlife feeding study or a long-term wildlife field study. In addition, if appropriate, the CCC and CMC are also related to a water quality characteristic, such as pH, salinity, or hardness. In many situations, states might want to adjust water quality criteria to reflect local environmental conditions, ecologically important species, and human exposure patterns.	To assess acute risk to fish and aquatic invertebrates, use the lowest LC50 or EC50 value for each ecosystem and aquatic organism (i.e., freshwater and/or estuarine/marine fish and aquatic invertebrate) and compare the aquatic peak EEC with the LC50 or EC50 value. If the resulting risk quotient is greater than a Level of Concern (LOC) of 0.5, then there is potential for acute risk to aquatic fish and invertebrates from use of the pesticide. If the resulting risk quotient is greater than an LOC of 0.1, but less than an LOC of 0.5, then risk to fish and aquatic invertebrates is presumed that may be mitigated by precautionary labeling statements or through labeled use restrictions. If the resulting risk quotient is less than an LOC of 0.1, but greater than an LOC of 0.05, then there is potential for risk to endangered aquatic fish and invertebrates. To assess chronic risk to aquatic fish and invertebrates, use the No Observed Adverse Effect Level (NOAEL) from the fish early life-stage or fish full life-cycle tests and the aquatic invertebrate early life-cycle test. Compare the NOAEL for aquatic fish with the 56-day average EEC and the NOAEL for aquatic invertebrates with the 21-day average EEC. If the resulting RQ is greater than an LOC of 1.0, then there is potential for chronic risks to these aquatic animals. To assess acute risk to aquatic plants, use the lowest EC50 or NOAEC from Tier 1 or Tier 2 aquatic plant growth tests on five aquatic plant species. Compare this endpoint with the EEC derived from Tier 1 or Tier 2 surface water modeling, as needed. If the resulting RQ is greater than an LOC of 1.0, then there is potential for acute risk to aquatic plants. To assess acute risk to endangered aquatic plants, use the lowest LC50 from aquatic plant growth tests on 5 aquatic plants. Compare this endpoint with the aquatic plant EEC. If the resulting RQ is greater than an LOC of 1.0, then there is potential for acute risk to endangered aquatic plants.

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MINIMUM DATA REQUIRED TO ESTABLISH LEVEL OF PROTECTION	To derive a criterion for freshwater aquatic organisms and their uses, the following should be available: (1) Results of acceptable acute tests with at least one species of freshwater animal in at least eight different families such that all of the following are included: the family Salmonidae in the class Osteichthyes; a second family in the class Osteichthyes, preferably a commercially or recreationally important warmwater species (i.e., bluegill, channel catfish, etc.); a third family in the phylum Chordata (may be in the class Osteichthyes or may be an amphibian, etc.); a planktonic crustacean (e.g., cladoceran, copepod, etc.); a benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish, etc.); an insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.); a family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca, etc.); a family in any order of insect or any phylum not represented. (2) Acute-chronic ratios with species of aquatic animals in at least three different families provided that of the three species: at least one is a fish; at least one is an invertebrate; at least one is an acutely sensitive freshwater species (the other two may be saltwater species). (3) Results of at least one acceptable test with a freshwater alga or vascular plant. (4) At least one acceptable bioconcentration factor determined with an appropriate freshwater species, if a maximum permissible tissue concentration is availble.	Examines the potential risks of the proposed pesticide uses to non-target fish and aquatic invertebrates in the freshwater and in the estuarine/marine environments if there is potential for pesticide to be used in these environments. Examines risks to non-target algae and aquatic plants when pesticide is an herbicide or fungicide. Aquatic toxicity test data required and associated indicator species include: (1) acute 96-hour toxicity test for freshwater fish - coldwater fish is the rainbow trout (*Salmo gairdneri)* and warmwater fish is the bluegill sunfish (*Lepomis macrochirus);* (2) acute 96-hour toxicity test for freshwater invertebrates - water flea (*Daphnia magna*); (3) acute 96-hour toxicity test for estuarine and marine fish - sheepshead minnow (*Cyprinodon variegatus*); (4) acute 96-hour toxicity test for estuarine and marine crustacean - mysid, penaeid, or grass shrimp; (5) acute toxicity for estuarine and marine mollusc - 96-hour flow-through shell deposition and 48-hour embryo-larvae studies on Eastern oyster (*Crassostrea virginica*); (6), (7) chronic fish early-life stage and fish full life-cycle studies on rainbow trout (*Salmo gairdneri)* or brook trout (*Salvelinus fontinalis*) and fathead minnow *(Pimephales promelas*); (8) aquatic invertebrate life-cycle - water flea, (*Daphnia magna)*; (9) fish bioaccumulation factor. Aquatic plant testing is required for all pesticides used outdoors. Tier 1 testing is to be performed on 5 aquatic plant species at the maximum proposed application rate on the pesticide label. The 5 aquatic plants to be tested in Tier 1include: duckweed (*Lemna gibba*)*;* marine diatom (*Skeletonema costatum*); blue-green alga (*Anabaena flos-aquae*); freshwater green alga (*Selenastrum capricornutum*); and freshwater diatom (unspecified species). The substance to be tested is the Typical End Use Product (TEP) rather than the Technical Grade Active Ingredient (TGAI). For any aquatic plant species exhibiting phytotoxic effects from Tier 1 testing, a Tier 2 test must be performed. Tier 2 testing is performed at dose rates less than the maximum label rate.

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SOURCE AND TYPE OF DATA COLLECTED	Collects all available data on the chemical concerning toxicity to, and bioaccumulation by, aquatic animals and plants; FDA action levels; chronic feeding studies and long-term field studies with wildlife species that regularly consume aquatic organisms.	Under FIFRA, the Agency is not responsible for producing the data needed to assess ecological risks. That burden is placed upon the applicants for pesticide registration. OPP requests certain toxicity data prior to performing an aquatic risk assessment. The following aquatic toxicological hazard data represent the full complement of aquatic testing that could be requested for an aquatic risk assessment: Tier 1 - 96-hour coldwater fish LC50; 96-hour warmwater fish LC50; 48-hour (or 96-hour) freshwater aquatic invertebrate LC50. Tier 2 - 96-hour estuarine/marine fish LC50; 96-hour estuarine/marine fish LC50; 48-hour oyster embryo-larvae EC50; 96-hour oyster shell deposition EC50; fish early life-stage No Observed Adverse Effect Level (NOAEL); aquatic invertebrate life-cycle NOAEL; fish bioaccumulation factor; and fish acetylcholinesterase levels. Tier 3 - fish full life-cycle NOAEL. Tier 4 - fish/aquatic invertebrate population effects in the field; simulated and actual field effects data on aquatic organisms. Registrants are also required to provide data on the fate and transport of pesticides in the environment. These fate data requirements include: hydrolysis, photodegradation in water, photodegradation in soil, aerobic soil metabolism, anaerobic soil metabolism, anaerobic aquatic metabolism, and aerobic aquatic metabolism, leaching and adsorption/desorption, and aquatic field dissipation.

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GENERAL CRITERIA FOR ACCEPTABLE STUDIES	Some general criteria are included in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses". These general criteria include: (1) All data that are used should be available in typed, dated, and signed hard copy with enough supporting information to indicate that acceptable test procedures were used and that the results are probably reliable. (2) In some cases it may be appropriate to obtain additional written information from the investigator, if possible. (3) Data on technical grade material may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material of concern should not be used. (4) For some highly volatile, hydrolyzable, or degradable materials it is probably appropriate to use only results of flow-through tests in which the concentrations of test material in the test solutions were measured often enough using acceptable analytical methods. (5) Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with non-resident species or previously exposed organisms may be used to provide auxiliary information but may not be used in the derivation of criteria.	To be determined as acceptable, or Core, studies must meet Subdivision E guidelines. OPP has published regulations which specify the data that are required for registration (i.e., 40 CFR part 158), and guidelines which provide recommended testing methods that are needed to produce the required data (i.e., Pesticide Assessment Guidelines - Subdivision E). In addition, Standard Evaluation Procedures (SEPs) have been developed for each type of data that is required for an ecological risk assessment. These SEPs explain the procedure used to evaluate ecological effects data submitted to OPP, and ensure comprehensive and consistent treatment of the science in reviews as well as providing interpretive policy guidance. These SEPs are published and are available through the National Technical Information Service (NTIS). Specific Standard Evaluation Procedure documents for aquatic organism tests include: (1) Ecological Risk Assessment - EPA-540/9-85-001; (2) Acute Toxicity Test for Freshwater Fish - EPA-540/9-85-006; (3) Acute Toxicity for Freshwater Invertebrates - EPA-540/9-85-005; (4) Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute Toxicity Test) - EPA-540/9-85-010; (5) Acute Toxicity Test for Estuarine and Marine Organisms (Estuarine Fish 96-Hour Acute Toxicity Test) - EPA-540/9-85-009; (6) Acute Toxicity Test for Estuarine and Marine Organisms (Mollusc 96-Hour Flow-Through Shell Deposition Study) - EPA-540/9-85-011; (7) Non-Target Plants: Growth and Reproduction of Aquatic Plants - Tiers 1 and 2 - EPA-540/9-86-134; (8) Fish Early Life-Stage - EPA 540/9-86-138; (9) Daphnia magna Life-Cycle (21-Day Renewal) Chronic Toxicity Test - EPA 540/9-86-141; and (10) Fish Life-Cycle Toxicity Tests - EPA 540/9-86-137.